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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,938	05/15/2006	Marvin J. Fritzler	66609.1US	8610

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
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1641

MAIL DATE	DELIVERY MODE
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12/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/541,938

Applicant(s)

FRITZLER, MARVIN J.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 6 and 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. Claims 1-8 are pending. Claims 3, 4, 6 and 7 are withdrawn. Claims 1, 2, 5 and 8 are under consideration

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e) as follows:
 3. The inventorship of the provision application is not the same with that of the instant application. Correction is required.

Response to Priority Arguments

4. A request for correction of inventorship in the provision application 60/440,326 has been received in the instant application. However, since the instant application contains the correct inventorship, the request should be submitted NOT to the instant application but to the provision application 60/440,326. See 37 CFR 1.48 (e) & (f)(2).

(e) **Provisional application** – deleting the name or names of the inventor or inventors . If a person or persons were named as an inventor or inventors in a provisional application through error without any deceptive intention on the part of such person or persons, an amendment may be filed in the *provisional*

application (emphasis added) deleting the name or names of the person or persons who were erroneously named. Amendment of the inventorship requires:

- (1) A request to correct the inventorship that sets forth the desired inventorship change;
- (2) A statement by the person or persons whose name or names are being deleted that the inventorship error occurred without deceptive intention on the part of such person or persons;
- (3) The processing fee set forth in § 1.17(q); and
- (4) If an assignment has been executed by any of the original named inventors, the written consent of the assignee (see § 3.73(b) of this chapter).

(f) (2) **Provisional application filing cover sheet corrects inventorship.** If the correct inventor or inventors are not named on filing a provisional application without a cover sheet under § 1.51(c)(1), the later submission of a cover sheet under § 1.51(c)(1) during the pendency of the application will act to correct the earlier identification of inventorship.

5. Until such time as the inventorship of the provisional application is corrected, priority is denied.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (f) he did not himself invent the subject matter sought to be patented.

7. Claims 1, 2, 4 and 8 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

Since priority to the provision application is denied, Eystathioy et al., (*Hybridoma and Hybridomics*. 2003. 22(2):79-86) anticipates the instant claims. Eystathioy discloses a monoclonal antibody that binds GW 182 protein and method of using it to detect GW 182 in serum sample. See abstract.

The authorship of this paper differs from the inventorship of the instant application, therefore, it is unclear whether applicant invents the claimed subject matter.

8. Claims 1, 2, 4 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Eystathioy et al (*Hybridoma and Hybridomics*. 2003. 22(2):79-86).

Since priority is not given back to the provisional application 60/440,326, the filing date of the instant application is 16 January 2004.

Eystathioy discloses the invention exactly as claimed. See abstract.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eystathioy et al (*Molecular Biology of the Cell*. April 2002. 13:1338-1351) in view of Kohler (*Science*. 1986. 233 (4770):1281-1286).

Eystathioy fully discloses GW ribonucleoprotein including a 182kDa protein designated GW182 and rabbit and human serum binding to the same.

Eystathioy differs in failing to specifically teach monoclonal antibodies to GW 182.

Kohler disclosed a method for producing hybridoma cell lines secreting monoclonal antibodies using lymphocyte fusion techniques. Kohler disclosed that polyclonal antibodies suffers from major disadvantages such as low titers, the polyclonal antibodies are heterogeneous, limited supply and that it is impossible to reproduce the same combination of specific antibodies in a new animal. In contrast, lymphocyte fusion provides the advantages of specificity, unlimited supply of antibody. The use of impure antigens still leads to pure antibody reagents. All specificities can be rescued. Enrichment or specific hybridomas is possible. A high level of antibody secretion is observed. The hybridoma cell lines can be manipulated to product antibodies not found in nature, and the method is general such that antibodies against any antigen may be produced. See page 1281.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to produce a monoclonal antibody against the protein

taught by Eystathioy using the method of Kohler because Kohler teaches that any substance that can elicit a humoral response can be used to prepare monoclonal antibodies, and that monoclonal antibodies provides advantages not found in polyclonal antibodies. These advantages include specificity of binding, homogeneity, and ability to be produced in unlimited quantities. The production of monoclonal antibodies allows the isolation of reagents with a unique and chosen specificity. Because all of the antibodies produced by descendants of one hybridoma cell are identical, monoclonal antibodies are powerful reagents for testing for the presence of a desired epitope. In addition, one unique advantage of hybridoma production is that impure antigens can be used to produce specific antibodies. A skilled artisan would have had a reasonable expectation of success and would have been motivated to use the techniques of Kohler to produce monoclonal antibodies to the GW 182 protein taught by Eystathioy because such techniques are well known in the art and provides advantages not found with polyclonal antibodies.

Response to Arguments

11. Applicant's arguments filed 09 July 2007 have been fully considered but they are not persuasive.

As stated above, priority to the provision application is denied since the inventorship has not been properly corrected.

The argument with respect to the 35 USC 103(a) rejection over Eystathioy in view of Kohler is not persuasive. The reference in this rejection has a publication date of April 2002 which is more than one year before the priority date of 14 May 2003, even if priority is granted.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date

of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday -- Thursday from 9:00 a.m. - 3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
12/17/07